

REMARKS

Status of the Claims.

Claims 1, 8-26, 29-34, 41-55, 62-72, 76-90, and 97-115 are pending with entry of this amendment, claims 2-7, 27, 28, 35-40, 56-61, 73-75, and 91-96 being cancelled and no claims being added herein. Claims 1, 8-26, 32, 34, 41-46, 50-55, 62-72, 76-84, 87, 90, 97-103, 106, 107, 111, and 113-115 are amended herein. These amendments introduce no new matter. Support is replete throughout the specification (e.g., in the claims as originally filed).

Election/Restriction.

Pursuant to a restriction requirement made final, Applicants have deleted non-elected subject matter with entry of this amendment. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

Information Disclosure Statement.

A Supplemental IDS (PTO form 1449) is provided herewith. Applicants expressly request again that the Examiner consider the references cited therein and properly make them of record in the prosecution.

Oath/Declaration.

The Examiner alleged that the oath or declaration is defective. A substitute oath/declaration is being executed and will be submitted shortly.

Objections to the specification.

The specification was objected to because the claim for priority at paragraph [0001] was allegedly improper because of the reference to "claims benefit". The priority claim in paragraph [0001] is amended herein thereby obviating this objection.

The specification was objected to because of an embedded hyperlink or other form of browser-executable code. At page 13, line 23. M.P.E.P. §7.29.03 states:

Examiners must review patent applications to make certain that hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not included in a patent application. Examples of a hyperlink or a browser-executable code are a URL placed **between these symbols "< >" and http:// followed by a URL address**. When a patent application with embedded hyperlinks and/or other forms of browser-executable code

issues as a patent (or is published as a patent application publication) and the patent document is placed on the USPTO web page, when the patent document is retrieved and viewed via a web browser, the URL is interpreted as a valid HTML code and it becomes a live web link. When a user clicks on the link with a mouse, the user will be transferred to another web page identified by the URL, if it exists, which could be a commercial web site. USPTO policy does not permit the USPTO to link to any commercial sites since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. [emphasis added]

The paragraph referenced by the Examiner has been amended so that it includes neither the "<" symbols nor "http://". Accordingly, the amended text is not a hyperlink or browser executable code and the Examiner's objection is obviated.

35 U.S.C. §112, Second Paragraph.

Claims 28, 32, 41, 43, 50-54, 56-85, 87, and 90-115 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite because the word "and" should be inserted before the last member of the Markush group in claims 28, 32, 54, 82, and 115. Claims 28, 32, 54, and 115 are amended to insert the word "and" thereby obviating this rejection.

Claims 32, 54, and 82 were rejected as allegedly indefinite because the recited groups are fatty acid groups, not phospholipids. Claims 32, 54, and 82 are amended herein to refer to "... a phospholipid comprising a fatty acid selected from ..." the list of recited groups, thereby obviating this rejection.

Claims 41-43 were rejected as allegedly lacking antecedent basis for the phrases "said first protecting group" and "said second protecting group". Claim 34 is amended herein to provide proper antecedent basis thereby obviating this rejection.

Claim 50 was rejected as allegedly indefinite in the recitation of "comprising". Claim 50 is amended in accordance with the Examiner's recommendation thereby obviating this rejection.

Claims 51-54 were rejected as allegedly indefinite in the recitation of "polypeptide" rather than "peptide". Claims 51-54 are amended herein to recite "peptide" thereby obviating this rejection.

Claims 56-64, 66-78, 83-85, and 91-96 were rejected as allegedly indefinite in the recitation of "said peptide". The amendments made herein clarify the recitation of peptide thereby obviating this rejection.

Claim 87 was rejected as lacking antecedent basis for the phrase "said organism", claim 90 was rejected as lacking antecedent basis for the phrase "said mammal", and claims 97-100 were rejected as lacking antecedent basis for the phrase "said organism". The amendments made herein provide proper antecedent basis for these claims thereby obviating this rejection.

Claims 102, 103, and 105 were rejected because of reference to "said peptide". These claims are amended to recite "said polypeptide" thereby obviating this rejection.

Claim 106 was rejected as allegedly indefinite because of the recitation of both inflammation and atherosclerosis. Dependent claims 11, 12, and 113 were similarly rejected. Claim 106 is amended to recite "A method of mitigating or preventing a coronary complication associated with an acute phase response to an inflammation in a mammal, said method comprising . . ." and claim 113 is similarly amended thereby obviating this rejection.

Objections to the claims.

Claims 11-14, 32, 33, 41, 54, 65-68, 82, and 100-115 were objected to for a variety of informalities as recited in paragraph 7 of the Office action. The claims are amended herein to eliminate these informalities thereby obviating these objections.

35 U.S.C. §112, First Paragraph.

Claim 111 was under 35 U.S.C. §112, first paragraph, as allegedly not enabling because the specification allegedly does not provide enablement for the mitigation or prevention of a coronary complication associated with Alzheimer's Disease or AIDS.

To expedite prosecution, Applicants have deleted reference to Alzheimer's Disease or AIDS in claim 111. Please note, however, that Applicants reserve the right to file subsequent applications claiming the canceled subject matter and the claim cancellations should not be construed as abandonment or agreement with the Examiner's position in the Office Action.

Obviousness-Type Double Patenting.

Claims 1-115 were rejected under the judicially created doctrine of obviousness-type double patenting in light of claims 1-102 of U.S. Patent 6,930,085. Applicants traverse.

The claims of U.S. Patent 6,930,085 are directed to compositions and methods utilizing the peptides of SEQ ID NO:9 and SEQ ID NO:2. In contrast, the present claims, as amended herein, pertain to compositions and methods comprising the amino acid sequence of SEQ ID NO:18. Claims 1-102 of U.S. Patent 6,930,085 offer no teaching or suggestion of this sequence. Accordingly, the obviousness-type double patenting rejection should be withdrawn.

35 U.S.C. §102.

Silkensen *et al.* (Office Action Paragraph 11).

Claims 1-6, 25-28, 49, 50, 101, and 102 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Silkensen *et al.* (1999) *J. Pept. Res.*, 54: 449-457. Applicants traverse.

According to the Examiner, Silkensen *et al.* teaches the peptide Clu-29 which corresponds to residues 2-17 of SEQ ID NO:2, and Clu-30, which comprises residues 1-8 of SEQ ID NO:18. This reference, however, does not teach a peptide that " ranges in length from 10 amino acids to 40 amino acids" and "comprises the amino acid sequence DQYYLRVTTVA, (SEQ ID NO:18)" as recited in the pending claims.

Silkensen *et al.* thus fails to teach or otherwise disclose all the features of the presently pending claims. Accordingly, this rejection under 35 U.S.C. §102(b) should be withdrawn.

WO 2002/22161 (Office Action, paragraph 12)

Claims 1-7, 25-28, 49, 55-61, 83-99, 106, 107, and 109-115 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by WO 2002/22161. Applicants traverse.

WO 2002/22161 allegedly teaches administering clusterin (*i.e.*, the full-length protein) in order to treat or prevent atherosclerosis and underlying and/or related diseases. This reference, however, does not teach a peptide that " ranges in length from 10 amino acids to 40 amino acids" and "comprises the amino acid sequence DQYYLRVTTVA, (SEQ ID NO:18)" as recited in the pending claims. Accordingly this rejection under 35 U.S.C. §102(e) should be withdrawn.

WO 91/05043 (Office Action, paragraph 14).

Claims 1-8, 25, 27, 28, 49, 55-62, 83, 86-100, 106, 107, 109, and 112-115 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by WO 91/05043. Applicants traverse.

According to the Examiner, this application teaches an isolated protein having the amino acid sequence recited in claim 17 because residues 113-122 correspond to SEQ ID NO:9, residues 36-353 allegedly correspond to SEQ ID NO:2, and residues 358-368 allegedly correspond to SEQ ID NO:9.

WO 91/05043, however, does not teach or otherwise disclose a peptide that "ranges in length from 10 amino acids to 40 amino acids" and "comprises the amino acid sequence

DQYYLRVTTVA, (SEQ ID NO:18)" as recited in the presently pending claims. Accordingly this rejection under 35 U.S.C. §102(b) should be withdrawn.

WO 0034469 (Office Action, paragraph 16).

Claims 1-6, 25, 27, 28, 55-60, 86-95, 97-100, 106, 107, and 112-115 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by WO 00/34469. According to the Examiner, WO 00/34469 teaches a clusterin-related peptide having the sequence recited in claims 10 and 16 because residues 2-14 of the '469's peptide of claim 16 correspond o residues 4-16 of Applicants SEQ ID NO:2 with the exception of S/N at position 8 corresponding to position 10 of SEQ ID NO:2. Applicants traverse.

WO 91/05043, however, does not teach or otherwise disclose a peptide that "ranges in length from 10 amino acids to 40 amino acids" and "comprises the amino acid sequence DQYYLRVTTVA, (SEQ ID NO:18)" as recited in the presently pending claims. Accordingly this rejection under 35 U.S.C. §102(b) should be withdrawn.

35 U.S.C. §103(a).

Claims 50 and 101-105 were rejected under 35 U.S.C. §103(a) as allegedly obvious in light of WO 2002/22161 as described above. The Examiner alleged that it would be obvious to one of skill in the art to provide the modulators of the WO 2002/22161 application in kit form as recited in claims 50 and 101-105 (*see*, Office Action paragraph 13). Claims 50, 101-103, and 105 were rejected under 35 U.S.C. §103(a) as allegedly obvious in light of WO 91/05043 as described above. Again the Examiner alleged that it would be obvious to one of skill in the art to provide the cytotoxic inhibitor of the WO 2002/22161 application in kit form (*see*, Office Action paragraph 16). Claims 25, 49, 50, 83, 101-103, 105, and 109 were rejected under 35 U.S.C. §103(a) as allegedly obvious in light of WO 00/34469. The Examiner alleged that it would be obvious to one of skill in the art to provide the clusterin-related peptide of the WO 00/34469 application combined with a pharmaceutically acceptable excipient or in kit form, optionally in unit dosage form and with instructions for use (*see*, Office Action paragraph 17). Claims 9-18 and 63-75 were rejected under 35 U.S.C. §103(a) as allegedly obvious in light of WO/0034469 in view of Borovsky *et al.* (U.S. Patent 5,358,934) (*see*, Office Action paragraph 18). According to the Examiner WO/0034469 does not teach modifying the N-terminus and/or C-terminus of the clusterin-related peptide with a protecting group and Borovsky is cited as teaching acetylating the N-terminus and amidating the C-terminus of peptides to inhibit proteolysis by metabolic enzymes. Claims 26, 84, 85, and 104 were

rejected under 35 U.S.C. §103(a) as allegedly obvious over WO 00/34469 further in view of Stern *et al.* (U.S. patent 6,086,918) (*see*, Office Action, paragraph 19). According to the Examiner WO 00/34469 does not teach oral administration of the clusterin-related peptide and Stern *et al.* is cited as teaching carrier compositions for oral administration. Applicants traverse.

In making the above-rejections the Examiner relies on the cited PCT applications as allegedly teaching the claimed sequences as described above under the §102 rejections. The presently pending claims, however, are amended to recite a peptide or polypeptide that "ranges in length from 10 amino acids to 40 amino acids" and that "comprises the amino acid sequence DQYYLRVTVA, (SEQ ID NO:18)". The cited references, individually, or in combination, however, offer no teaching or suggestion of such a peptide. Accordingly the rejections under 35 U.S.C. §103(a) should be withdrawn.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 267-4161.

Beyer Weaver, LLP
500 12th Street, Suite 200
Oakland, CA 94607
tel: (510) 663-1100
fax: (510) 663-0920

Respectfully submitted,



Tom Hunter
Reg. No: 38,498